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STRADLING Yocca CARLSON & RAUTH

A PROFESSIONAL CORPORATION

ATTORNEYS AT LAW

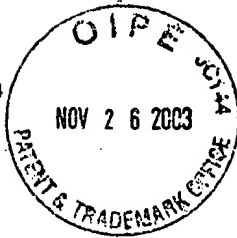
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CERTIFICATE OF EXPRESS MAIL

I hereby certify that on November 26, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage in an envelope addressed to: Mail Stop: Patent Term Extension, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. § 1.8(a)

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APPLICATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. § 156

Mail Stop: Patent Term Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

RE: Application for Patent Term Extension Pursuant to 35 U.S.C. § 156 (37 C.F.R. § 1.740) United States Patent Number 5,836,965

Dear Commissioner:

Enclosed is an application for patent term extension pursuant to 37 C.F.R. § 1.740. The owner (assignee) of record, Medtronic Vascular (formerly Medtronic AVE) is submitting this application. All rights in United States Patent Number (USPN) 5,836,965 are held by and vested in Medtronic Vascular a Delaware Corporation and a wholly owned subsidiary of Medtronic, Inc., a Delaware company. Medtronic Vascular's corporate headquarters are located at 3576 Unocal Place, Santa Rosa, CA 95403. A brief chain of title summary follows.

Brad Jendersee and Robert Lashinski are joint inventors of USPN 5,836,965 (UNPASN 08/478,192) which is a continuation-in-part of United States Patent Application Serial Number (USPASN) 08/326,023 filed October 19, 1994, now abandoned. Jendersee and Lashinski assigned their entire right, title and interest in USPASN 08/478,192), together with all divisions and continuations to Applied Vascular Engineering and its successors and assigns on July 20, 1995. This

assignment was recorded in the records of the United States Patent and Trademark Office on Reel 7689, Frame 0104. Applied Vascular Engineering then assigned its entire rights, title and interests to Arterial Vascular Engineering, and its successors and assigns. This assignment was recorded in the records of the United States Patent and Trademark Office on Reel 786389, Frame 0672.

On January 30th, 1996 Applied Vascular Engineering, Inc. changed its name to Arterial Vascular Engineering, Inc. Applied Vascular Engineering then assigned its entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Arterial Vascular Engineering. This assignment was executed January 30th, 1996 and was recorded March 20, 1996. A complete microfilm copy is available in the USPTO records on reel 8522, frame 0049.

Medtronic, Inc. acquired the assets of Arterial Vascular Engineering (AVE) through acquisition on January 29th, 1999 and formed a new Delaware Corporation named Medtronic AVE. Arterial Vascular Engineering assigned its entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Medtronic AVE. This assignment was executed January 28th, 1999 and was recorded January 31, 1999. A complete microfilm copy is available in the USPTO records on reel 011258, frame 0053.

Subsequently, Medtronic AVE changed its name to Medtronic Vascular, the present applicant, wherein all right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part now reside. Therefore, the application for patent term extension, Medtronic Vascular, is the owner of all rights title and interests in USPN 5,836,965, the subject patent of the present patent term extension application.

Documents supporting the above title chain for USPN 5,836,965 can be found in Appendix A of this application for patent term extension.

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- 1) Complete Identification of the Approved Product by appropriate chemical and generic name, physical structure or characteristics:

The approved product is an over-the-wire coronary stent system for use in patients with symptomatic ischemic heart disease due to discrete single de novo and restenotic lesions. The FDA product code is MAF for Stents, Coronary. The Medtronic Vascular stent marketed as the "S8 Over-the-Wire System" or alternatively under the trademarked name "Driver Stent Delivery System." The System includes a cobalt-based modular stent mounted on a balloon catheter as depicted in Figure 1 below¹. Figure 2 A and B² depict the approved the S8 stent delivery system with the stent crowns securely encapsulated by balloon material.

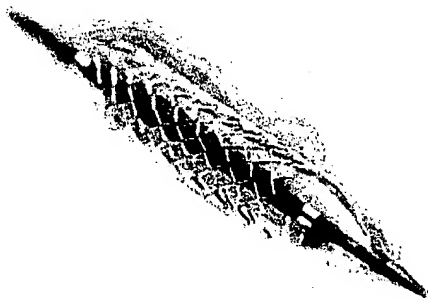


Figure 1

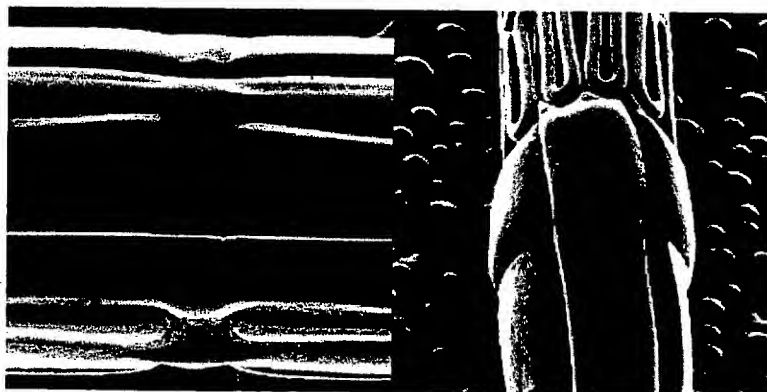


Figure 2 A and B

¹ See http://www.medtronic.com/medtronic_vascular/cs_drivermx.html

² *Id*

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- 2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred:

The Federal Statute under which regulatory review took place for the Medtronic Vascular's S8 Over-the-Wire System is 37 C.F.R. §814.

- 3) The date on which the product received permission for commercial marketing or use under the provision of law which the applicable regulatory review period occurred.

The Medtronic Vascular S8 Over-the-Wire System was approved for marketing October 1, 2003.

- 4) Statement that the present application is being submitted within the sixty day period permitted for submission and an identification of the date of the last day on which the application could be submitted.

The present application for patent term extension is being submitted with the sixty day period permitted for submission pursuant to 37 C.F.R. §1.720(f). The last day for submission of the present application is November 30, 2003. However, because November 30, 2003 is a Sunday, this application may be mailed December 1, 2003.

- 5) The complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue and the expiration date.

The present application for extension is for United States Patent Number 5,836,965 issued November 17, 1998 and expiring November 17, 2015. The inventors are Brad Jendersee and Robert Lashinski.

- 6) A copy of the entire patent for which extension is being sought, including the entire specification, claims and drawing.

A copy of U.S. patent number 5,836,965 is attached as Appendix B.

- 7) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent.

There are no disclaimers, certificates of correction or reexamination certificates issued on U.S. patent number 5,836,965. A copy of the maintenance fee payment record is provided as Appendix C.

- 8) Statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claims reads on the approved product.

United States patent number 5,836,965 claims the S8 Over-the-Wire Coronary Stent System approved October 1, 2003 and a method for treating narrowing vessels using the approved S8 stent. The applicant asserts that claims 1-5, claim 7-13 read on the approved device and that claims 6 and 14 read on the method of using the approved device.

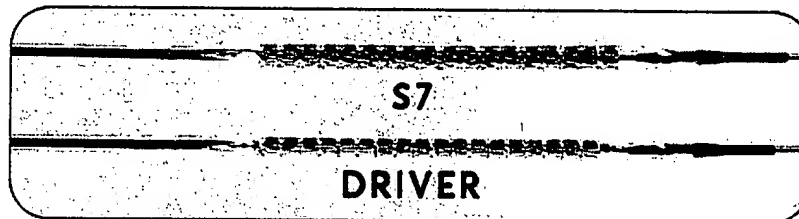
In particular, claim 1 reads on the approved device as follows:

Claim Chart Comparing Claim 1 of U.S. Patent 5,836,965 element-by-element with the S8 Over-the-Wire Coronary Stent

Claim 1 of U.S. Patent 5,836,965	Corresponding Features of the S8 Over-the-Wire Coronary Stent System
1. An endovascular support device for implantation in a vessel within the human body comprising:	The S8 is a coronary stent is an endovascular device and is approved for use in treating vascular occlusions including de novo and restenotic lesions of the coronary artery. Thus the S8 Over-the-Wire Coronary Stent System is intended for implantation in a vessel within the human body.
at least one compressible stent means mounted on a balloon of a balloon catheter; and	Figures 1 and Figure 3 clearly show the approved S8 stent mounted on the balloon of a balloon catheter. Figure 1 of this application shows the approved device in an expanded form. Compare Figure 1 with Figure 4 of this application where the approved device has been compressed onto the balloon of the balloon catheter.
wherein said at least one compressible stent means is encapsulated by said balloon of said balloon catheter	Figure 2 of this application (above) depicts the approved the S8 stent delivery system with the stent crowns securely encapsulated by balloon material.

The pictures and Figures that follow correlate to the claim elements discussed in the Claim Chart on the preceding page and clearly demonstrate that Claim 1 of U.S. patent 5,836,965 (the '965 patent) reads on the S8 Over-the-Wire Coronary Stent System.

Figure 3 (below) of this application depicts the "Driver" (AKA S8Coronary stent) compressed onto catheter for delivery to an affected vessel.³



Note how the individual segments are aligned parallel to the balloon axis when the S8 stent is in the compressed state. Therefore, based on the analysis above the Applicant respectfully asserts that Claim 1 of United States Patent number 5,836,965 reads on the approved device, the Medtronic Vascular S8 Over-the-Wire Coronary Stent.

Figure 1 of this application showing the S8 stent balloon mounted and forcibly expanded.



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In particular, claim 6 reads on a method for treating narrowing of vessels within humans using the approved device as follows:

Claim Chart Comparing Claim 6 of U.S. Patent 5,836,965 element-by-element with the method of using the S8 Over-the-Wire Coronary Stent to treat narrowing of the vessels.

Claim 6 of U.S. Patent 5,836,965	Corresponding Features of the S8 Over-the-Wire Coronary Stent System
6. A method for treating narrowing of vessels within humans comprising the steps of:	"The Medtronic Vascular DRIVER (S8 stent) Multi-Exchange Coronary Stent Delivery System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete <i>de novo</i> or restenotic lesions with reference vessel diameters of 3.0 mm to 4.0 mm and ≤ 30 mm in length using direct stenting or predilatation." ³
providing at least one endovascular support device;	The S8 stent is an endovascular support device and at least one approved S8 stent may be used to treat narrowing of a vessel. For example, the "Warnings and Precaution" section of the Medtronic Vascular web site devoted to the approved S8 stent states, in part: "When multiple stents are required, stent materials should be of similar composition." ⁴
mounting the at least one endovascular support device on a balloon of a balloon catheter	Figures 1, 2 and 3 of this application show the approved device mounted on a balloon in both the expanded and compressed state. Therefore, at least one endovascular support is mounted on a balloon of a balloon catheter.
anchoring the at least one endovascular support device to the balloon by encapsulation of the at least one endovascular support device by the balloon;	Figure 2 of this application (above) depicts the approved the S8 stent delivery system with the stent crowns securely encapsulated by balloon material. Thus at least one endovascular support device has been anchored to the balloon by encapsulation of the at least one endovascular support device by the balloon. See Figure 2 A and B of this application for a scanning electron microscope photograph clearly showing the balloon material encapsulating the endovascular support device.

³ See http://www.medtronic.com/medtronic_vascular/cs_drivermx_warnings.html

⁴ *Id*

Claim 6 of U.S. Patent 5,836,965	Corresponding Features of the S8 Over-the-Wire Coronary Stent System
advancing the balloon catheter and the at least one encapsulated endovascular support device to an area to be treated within the vessels;	"The Medtronic Vascular DRIVER (S8 stent) Multi-Exchange Coronary Stent Delivery System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete <i>de novo</i> or restenotic lesions with reference vessel diameters of 3.0 mm to 4.0 mm and ≤ 30 mm in length using direct stenting or predilatation." ⁵ The preceding quotation taken directly from the indications for use section of the Medtronic Driver web site (see foot note 4) clearly demonstrates that advancing the balloon catheter and the at least one endovascular support device to an area of the affected vessel is prerequisite to direct stenting or predilatation. Furthermore, the approved Driver Stent (S8 stent) is depicted in Figures 1, 2 and 3 mounted on a balloon catheter intended for insertion and into a patient's vascular system and advanced to a site of narrowing. Persons having ordinary skill in the art of intervention cardiology would know that advancing a balloon catheter having a stent mounted thereon would be inherent in the method of using the approved device.
inflating the balloon of the balloon catheter to expand the at least one encapsulated endovascular support device within the area to be treated; and	Figure 1 of this application depicts the S8 stent in expanded stated following balloon inflation. Figure 4 (below) of this application depicts at least one expanded S8 stent within the treatment area.
deflating the balloon of the balloon catheter so that the balloon pulls away from the at least one endovascular support device.	The balloon is deflated following the inflating step to facilitate catheter removal from the patent. This step would be recognized as at least inherent to one having ordinary skill in the art of interventional cardiology.

⁵ See http://www.medtronic.com/medtronic_vascular/cs_drivermx_warnings.html

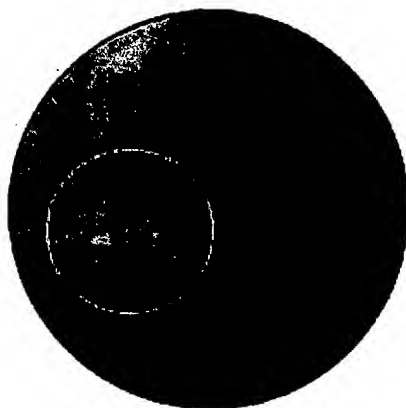
Figure 2 A and B (below) depicting different views of the *Secure Technology*TM endovascular device (stent) retention system. Both views show the material of a balloon catheter encapsulating the approved product (an endovascular support device AKA the S8, or DriverTM vascular stent system).



Figure 2 A

Figure 2 B

Figure 4 (below) depicts at least one expanded S8 stent deployed within a previously narrowed vessel.⁵



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- 9) The relevant dates and information pursuant to 35 U.S.C. §156(g) to enable the Secretary of Health and Human Services to determine the applicable review period:
- A) The effective date of the investigational device exemption (IDE) and the IDE number:
- 1) Conditional approval of the Applicant's IDE was dated December 20, 2001 and signed by Dr. Bram Zuckerman, Acting Director, Division of Cardiovascular and Respiratory Diseases.
 - 2) The Applicant's IDE number is G010301, G010301/A1, A2 and A3.
- B) The date on which the application for product approval under Section 515 of the Federal Food Drug and Cosmetic Act was initially submitted and the number of the application.
- 1) A Pre-market Approval application (PMA) for the S8 Over-the-Wire Coronary Stent System was submitted April 9, 2003.
 - 2) The PMA number is P030009.
- C) The date on which the application was approved.
- The S8 Over-the-Wire Coronary Stent System PMA was approved on October 1, 2003.

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- 10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

No.	FDA Reviewer	Date	Description
G010301	Carolyn Vaughan	21-Nov-01	Original Driver Over-the-Wire Delivery System IDE Submission
G010301 / A001	Carolyn Vaughan	29-Nov-01	Submission provided on CD-ROM
G010301 / A002	Carolyn Vaughan	12-Dec-01	Histopathology/photomicrographs sent for GLP - 237
G010301 / A003	Carolyn Vaughan	14-Dec-01	List of Investigational Sites
NA	Bram Zuckerman	20-Dec-01	Conditional Approval Letter received from FDA
NA	NA	21-Dec-01	Fax sent to accounts informing them of conditional approval from FDA
G010301 / S001	Bram Zuckerman	01-Feb-02	Response to FDA Conditional Approval Letter Dated December 20, 2001
G010301 / S002	IDE Doc. Mail Ctr	05-Feb-02	Request for addition of patient guide to supply to patients
NA	NA	08-Feb-02	First patient implant for IDE Trial
G010301 / S003	IDE Doc. Mail Ctr	09-Apr-02	Report of status with ongoing animal studies
G010301 / S004	IDE Doc. Mail Ctr	11-Apr-02	Request extension to deadlines put forth in conditional approval letter
G010301 / S005	IDE Doc. Mail Ctr	22-Apr-02	Request approval for addition of 10 clinical trial sites
NA	NA	19-Apr-02	Teleconference regarding statistical questions received from the Driver conditional approval letter.
G010301 / S006	Donna-Bea Tillman	17-May-02	Response to FDA Conditional Approval Letter submitted
G010301 / S006	Donna-Bea Tillman	10-Jun-02	Approval of Driver IDE received from FDA
G010301 / S007	IDE Doc. Mail Ctr	17-Jun-02	6-Month Clinical Site Update submitted

- 10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities. (Continued).

No.	FDA Reviewer	Date	Description
NA	Ashley Boam	19-Aug-02	FDA determines based on new material of stent, the Driver PMA submission must be an original PMA, not a PMA supplement
G010301 / S008	IDE Doc. Mail Ctr	26-Aug-02	Report of status with ongoing animal studies
NA	NA	25-Sep-02	Last patient implant for IDE Trial
G010301 / S009	Bram Zuckerman	17-Oct-02	Report of status with ongoing animal studies
G010301 / S010	IDE Doc. Mail Ctr	23-Dec-02	Submission to FDA: Response to letter dated 11/14/2002 Final Animal Study Report (FS81)
G010301 / S011	IDE Doc. Mail Ctr	15-Jan-03	Submission response to request for additional information
G010301 / S012	IDE Doc. Mail Ctr	16-Jan-03	Annual Report Submitted
NA	Sue Bowley/ Ashley Boam	28-Feb-03	Teleconference regarding inclusion of 270-day clinical data as PMA Amendment.
P030009	PMA Doc Mail Ctr	9-Apr-03	Original FDA PMA Submission of Driver Coronary Stent Systems
P030009	Bram Zuckerman	23-May-03	FDA agreed to file PMA
P030009 / A001	PMA Doc Mail Ctr	3-Jul-03	Response submitted to FDA regarding questions from email dtd 27-May-03
P030009 / A002	PMA Doc Mail Ctr	11-Aug-03	270 day clinical data, changes to the packaging of the Over-The-Wire and Rapid Exchange delivery systems and proposed manufacturing changes to the Multi-Exchange delivery system
P030009 / A003	PMA Doc Mail Ctr	13-Aug-03	Response submitted to FDA regarding questions from email dated 12-Jul-03
P030009 / A004	PMA Doc Mail Ctr	15-Aug-03	Authorization letter for the FDA to discuss Driver PMA / STED with MHLW in Japan
P030009	Sue Bowley	19-Aug-03	Request from FDA for an additional hard copy of PMA Amendment which included 270d clinical data.
P030009 / A005	PMA Doc Mail Ctr	21-Aug-03	To notify FDA of findings from an internal audit performed by the Atlanta Cardiovascular Research Institute (ACRI) related to animal study FS70

- 10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities. (Continued)

No.	FDA Reviewer	Date	Description
NA	Sue Bowley/ Steve Hilbert	21-Aug-03	Samples of the OTW delivery system provided to reviewers at the request of FDA.
NA	NA	21-Aug-03	STED Desk Copies submitted to FDA
P030009	Ashley Boam	22-Aug-03	FDA confirmed with MHLW permission for cooperative review of STED
P030009 / A006	PMA Doc Mail Ctr	5-Sep-03	Request the withdrawal of Nutek Corp, located in Hayward, CA, from our list of sterilization facilities for the Driver coronary stent systems
NA	Sue Bowley/ Ashley Boam	14-Sep-03	Conclusion reached regarding format of compliance chart
P030009	Ashley Boam	22-Sep-03	Agreement with FDA to include claim for direct stenting in IFU
P030009 / A007	PMA Doc Mail Ctr	22-Sep-03	Response submitted to FDA regarding questions from email dated 17-Sep-03
P030009	Sue Bowley	25-Sep-03	90-day Status e-mail received
P030009 / A008	PMA Doc Mail Ctr	29-Sep-03	Response to FDA questions on final labeling, biomaterials compendium and conditions of approval letter
P030003	Bram Zuckerman	1-Oct-03	Driver PMA Approval received from FDA
P030009 / A009	PMA Doc Mail Ctr	8-Oct-03	Final Labeling

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- 11) Statement that in the opinion of the applicant that the patent is eligible for extension and a statement as to the length of extension claimed, including how the extension was calculated.

The applicant respectfully asserts that United States Patent Number 5,836,965 is eligible for extension. The applicant has demonstrated that at least one claim of U.S. Patent 5,836,965 reads on the approved device (S8 Over-the-Wire Coronary Stent) and that this application for extension is being timely filed.

The applicant respectfully asserts that U.S. Patent 5,836,965 is eligible for a 413 day extension as calculated pursuant to 37 CFR §1.777.

Calculations Under 37 CFR §1.777

1. Calculations under 37 CFR §1.777 (c)(1)

Determine the number of days in the period beginning on the date a clinical investigation on humans involving the device began and ending the date the PMA was initially submitted.

- i) Clinical investigations on humans are deemed to have begun on the date that the FDA determines that an IDE required under section 520(g) of the FDCA (21 U.S.C. 360j (g) is substantially complete. In this case the records indicated that on December 20, 2001 the Medtronic Vascular IDE number G010301, G010301/A1, A2 and A3 received a Conditional Approval. Thus, this date will be used for the initial calculations .
- ii) The PMA was initially filed April 9, 2003.
- iii) The experimental period is thus calculated as the time between December 20, 2001 and April 9, 2003, or **476 days**.

2. Calculations under 37 CFR §1.777 (c)(2)

Determine the number of days in the period beginning on the date the PMA was initially filed and ending on the date the PMA was approved.

The PMA was initially submitted April 9, 2003 and was approved October 1, 2003. Thus the approval period was **175 days**.

The Sum of 37 CFR §1.777 c(1) and 37 CFR §1.777 (c)(2) equals 651 days.

3. Calculations under 37 CFR §1.777 (d)(1)

- i) Subtract the number of days in the periods (c)(1) and (c)2 of this section which were on and before the date the patent issued.

Zero days in period (c)(1) for U.S. Patent 5,836,965.

- ii) Subtract the number of days in the periods (c)(1) and (c)2 of this section during which the applicant did not act with due diligence.

Zero for U.S. Patent 5,836,965.

- iii) Subtract one-half the number of days remaining in the period defined by (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii).

238 days for U.S. Patent 5,836,965.

Therefore, the maximum extension available for U.S. patent number 5,836,965 For U.S. is $476 \text{ (from step 3 (i))} + 175 \text{ (from step 2)} - 238 \text{ (from step 3 (iii))} = 413$ days.

4. Calculations Under 37 CFR §1.777 (d)(2)

Determine the number of days shortened by a terminal disclaimer.

Zero for U.S. Patent 5,836,965

5. Calculations Under 37 CFR §1.777 (d)(3)

Section (d)3 requires that 14 years be added to the date the PMA was approved, this equals the longest possible extension available (14 years from the approval date) in this case the 37 CFR §1.777 (d)(3) date is October 1, 2017).

6. Calculations Under 37 CFR §1.777 (d)(4)

The new expiration date is January 4, 2017 which is before October 1, 2017. Thus United States Patent 5,836,965 is eligible for the entire 413 day extension as calculated above.

7. Calculations Under 37 CFR §1.777 (d)(5)

United States Patent number 5,836,965 was filed after September 24, 1984.

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- 12) Statement that the applicant acknowledges a duty to disclose to the Commissioner of Patents and trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

The applicant acknowledges his duty to disclose to the Commissioner of Patents and trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought. The applicant has no disclosures to that are material to the determination of entitlement to the extension sought.

- 13) The prescribed fee for receiving and acting upon the application for extension.

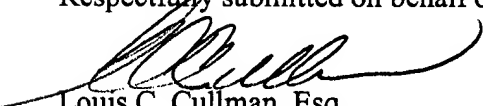
The Commissioner is hereby authorized to charge payment of the patent term extension application fee pursuant to 37 C.F.R. §1.20 (j)(1) in the amount of \$1,120.00 to Deposit Account number 01-2525.

- 14) The name address and telephone number of the person to whom inquires and correspondences relating to the application for patent term extension are to be directed.

Michael J. Jaro, Esq.
Chief Patent Counsel
Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403

(707) 566-1746

Respectfully submitted on behalf of the applicant,


Louis C. Cullman, Esq.
USPTO Reg. No. 39,645
Stradling Yocca Carlson & Rauth

P-1906.01

ASSIGNMENT

WHEREAS, WE, BRADLEY JENDERSEE, having a residential address of 1848 Castle Drive, Petaluma, California 94954, ROBERT LASHINSKI, having a residential address of 409 Princess Way, Windsor, California 95492, and MICHAEL D. BONEAU, having a residential address of 993-6 Asilomar Terrace, Sunnyvale, California 94086, and all being citizens of the United States of America, have invented a certain new and useful STENT DELIVERY AND DEPLOYMENT METHOD, for which U.S. Patent Application Number 08/478,192, was filed on June 7, 1995; and

WHEREAS, APPLIED VASCULAR ENGINEERING, INC., a Delaware corporation having an office at 5345 Skylane Boulevard, Santa Rosa, California, 95403, is desirous of obtaining the entire right, title and interest in, to and under the said application.

NOW THEREFORE, in consideration of a good and valuable consideration, the receipt of which is hereby acknowledged, WE, BRADLEY JENDERSEE, ROBERT LASHINSKI, and MICHAEL D. BONEAU have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over unto the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns my entire right, title and interest in, to and under the said invention and the said application for Patent, a copy of which as filed in the United States Patent Office is contained in File No. P-1906.01 in the Law Offices of James E. Erkin, a Professional Corporation, 1301 Shoreway Road, Suite 324, Belmont, California, 94002, and all divisions, continuations and all Patents of the United States which may be granted thereon and all applications for Patents which may be granted for said invention in any country

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or countries foreign to the United States, and all Patents which may be granted for said invention in any country or countries foreign to the United States, and to all extensions, renewals and reissues thereof, and the right to claim priority under the International Convention for the Protection of Industrial Property; and WE hereby authorize and request the Commissioner of Patents and Trademarks of the United States, and any official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue, all Patent for said invention to the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns, in accordance with this instrument.

AND WE hereby covenant that we have the full right to convey our entire interest herein assigned, and that we have not executed, and will not execute, any agreement in conflict therewith.

AND WE hereby further covenant and agree that we will communicate to the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns, any facts known to us respecting said invention, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths and generally do everything possible to aid the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns to obtain and enforce proper patent protection for said invention in all countries.

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P-1906.01

IN TESTIMONY WHEREOF, WE have hereunto set our hands and seal this 20
day of July 1995.

Bradley Jendersee
BRADLEY JENDERSEE

Robert Lashinski
ROBERT LASHINSKI

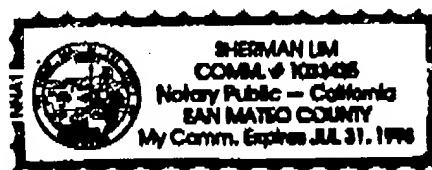
Michael D. Boneau
MICHAEL D. BONEAU

STATE OF CALIFORNIA)
COUNTY OF San Mateo) ss.

On this 20 day of July 1995, before me, Sherman Lim the
undersigned Notary Public, personally appeared BRADLEY JENDERSEE, personally known
to me or proved to me on the basis of satisfactory evidence to be the persons whose names are
subscribed to the within instrument, and acknowledged that they executed it.

WITNESS my hand and official seal.

Sherman Lim
Notary Public



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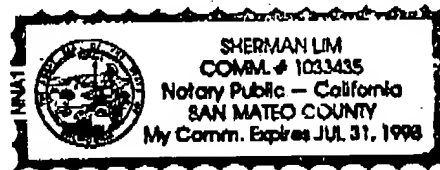
P-1906.01

STATE OF CALIFORNIA
COUNTY OF San Mateo } ss.

On this 20 day of July 1995, before me, Sherman Lim the undersigned Notary Public, personally appeared ROBERT LASHINSKI, personally known to me or proved to me on the basis of satisfactory evidence to be the persons whose names are subscribed to the within instrument, and acknowledged that they executed it.

WITNESS my hand and official seal.

Sherman Lim
Notary Public

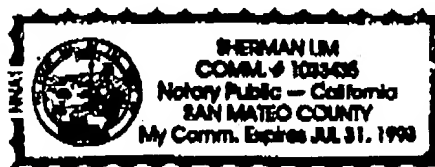


STATE OF CALIFORNIA
COUNTY OF San Mateo } ss.

On this 20 day of July 1995, before me, Sherman Lim the undersigned Notary Public, personally appeared MICHAEL D. BONEAU, personally known to me or proved to me on the basis of satisfactory evidence to be the persons whose names are subscribed to the within instrument, and acknowledged that they executed it.

WITNESS my hand and official seal.

Sherman Lim
Notary Public



FROM RICHARDS, LAYTON & FINGER #10

(WED) 1. 28' 98 15:03/ST. 15:07/NO. 4861878583 P 3

Exhibit A

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
ARTERIAL VASCULAR ENGINEERING, INC.

ARTICLE 1 - NAME

The name of the corporation shall be Medtronic AVE, Inc.

ARTICLE 2 - REGISTERED OFFICE AND AGENT

The registered office of the corporation in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle, Delaware, 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE 3 - PURPOSES

The nature of the business or purposes to be conducted or promoted by the corporation is to engage in any lawful acts and activities for which corporations may be organized under the General Corporation Law of Delaware.

ARTICLE 4 - STOCK

The aggregate number of shares the corporation has authority to issue shall be 2,500 shares of Common Stock, \$.01 par value. Holders of Common Stock shall be entitled to one vote for each share of Common Stock held of record.

ARTICLE 5 - RIGHTS OF STOCKHOLDERS

5.1) No Preemptive Rights. No holder of shares of the corporation of any class now or hereafter authorized has any preferential or preemptive right to subscribe for, purchase or receive any shares of the corporation of any class now or hereafter authorized, or any options or warrants for such shares, which may at any time be issued, sold or offered for sale by the corporation.

5.2) No Cumulative Voting Rights. No holder of shares of the corporation of any class now or hereafter authorized shall be entitled to cumulative voting.

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FROM RICHARDS, LAYTON & FINGER #10

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ARTICLE 6 - MEETINGS AND BOOKS

6.1) Meetings of Stockholders and Election of Directors. Meetings of stockholders may be held within or outside the State of Delaware, as the Bylaws may provide. Elections of directors need not be by written ballot unless and except to the extent that the Bylaws so provide.

6.2) Corporate Books. The books of the corporation may be kept within or (subject to any provision contained in the statutes) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the corporation.

ARTICLE 7 - LIMITATION OF DIRECTOR LIABILITY

7.1) Limitation of Liability. A director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which the director derived an improper personal benefit. If the Delaware General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

7.2) Amendment of this Article. Any repeal or modification of this Article 7 shall be prospective and shall not affect the rights under this Article 7 in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

ARTICLE 8 - BYLAWS

The Board of Directors is expressly authorized to make and alter Bylaws of this corporation, subject to the power of the stockholders to change or repeal such Bylaws and subject to any other limitations on such authority provided by the General Corporation Law of Delaware.

3200631-8

Certificate Under 37 C.F.R. § 3.73(b)Applicants: Bradly A. Jendersee, et al.Application No.: 09/189,597 Filed: November 10, 1998Entitled: Stent Delivery and Deployment MethodMedtronic AVE Inc., a Corporation

(Name of Assignee)

(Type of Assignee, e.g., Corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest, or
2. ☐ an assignee of an undivided part interest

in the patent application/patent identified above by virtue of either:

- A. ☐ An Assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

- B. ☒ A chain of title from the inventor of the patent application identified above to the current assignee as shown below:

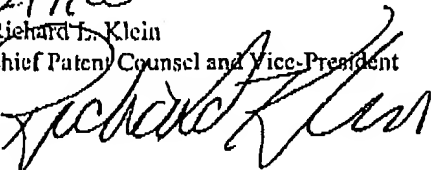
1. From: Bradly A. Jendersee, et al. To: Applied Vascular Engineering, Inc.
The document was recorded in the Patent and Trademark Office at
Reel 7689, Frame 0104, or for which a copy thereof is attached.
2. From: Applied Vascular Engineering, Inc. To: Arterial Vascular Engineering
The document was recorded in the Patent and Trademark Office at
Reel 7863, Frame 0672, or for which a copy thereof is attached.
3. From: Arterial Vascular Engineering To: Medtronic AVE Inc.
The document was recorded in the Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the PTO. See MPEP 302-302.8]

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee.

Date: 2/7/00Name: Richard L. KleinTitle: Chief Patent Counsel and Vice-PresidentSignature: **BEST AVAILABLE COPY**



US005836965A

United States Patent [19]
Jendersee et al.

[11] **Patent Number:** **5,836,965**
[45] **Date of Patent:** **Nov. 17, 1998**

[54] **STENT DELIVERY AND DEPLOYMENT METHOD**

[76] **Inventors:** **Brad Jendersee; Robert Lashinski,**
both of 5345 Skylane Blvd., Santa
Rosa, Calif. 95403

[21] **Appl. No.:** **478,192**

[22] **Filed:** **Jun. 7, 1995**

Related U.S. Application Data

[63] **Continuation-in-part of Ser. No. 326,023, Oct. 19, 1994,**
abandoned.

[51] **Int. Cl.⁶** **A61M 29/00**

[52] **U.S. Cl.** **606/198; 606/194; 623/1;**
623/12; 604/96

[58] **Field of Search** 606/1, 108, 191,
606/194, 195, 198, 200; 604/96-104; 623/1,
12

[56] **References Cited**

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5,108,416 4/1992 Ryan et al. .
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Primary Examiner—Michael Buiz

Assistant Examiner—William Lewis

Attorney, Agent, or Firm—Richard L. Klein

[57] **ABSTRACT**

A encapsulated stent device for implantation within the vascular system includes a balloon of a balloon catheter formed around and adhered to a wire-like stent so that the outer surface of the device is more regular for delivery through the vascular system without an exterior sheath. The encapsulation securely anchors the stent to the balloon and maintains a low profile for negotiation of tortuous and narrowed vessels. Encapsulation requires placement of the stent over the balloon, placement of a sheath over the stent on the balloon, heating and preferably pressurization of the balloon to cause it to expand around the stent within the sheath, and cooling while preferably maintaining pressure to cause the balloon to adhere to the stent and to set the shape of the expanded balloon. Retainers may be placed at the distal and/or proximal ends of the stent during the encapsulation process, or the balloon material may expand to form retainers. The balloon defines at least three folded wings for symmetrical expansion of the stent, and one or more connected or non-connected stents may be encapsulated depending upon the area to be treated.

14 Claims, 5 Drawing Sheets

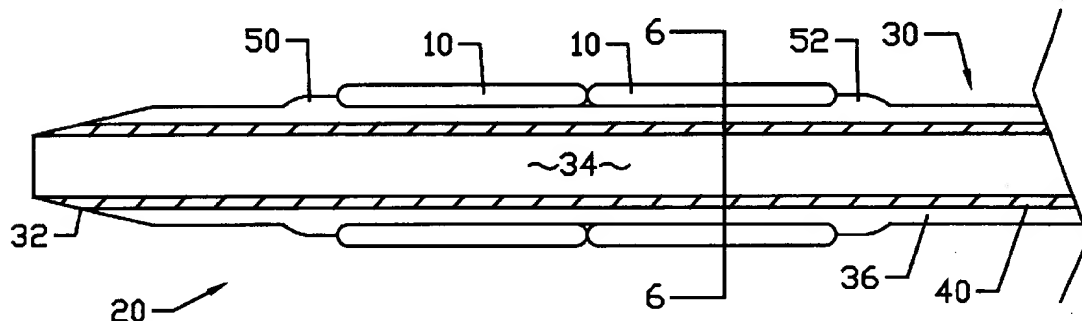


FIGURE 1

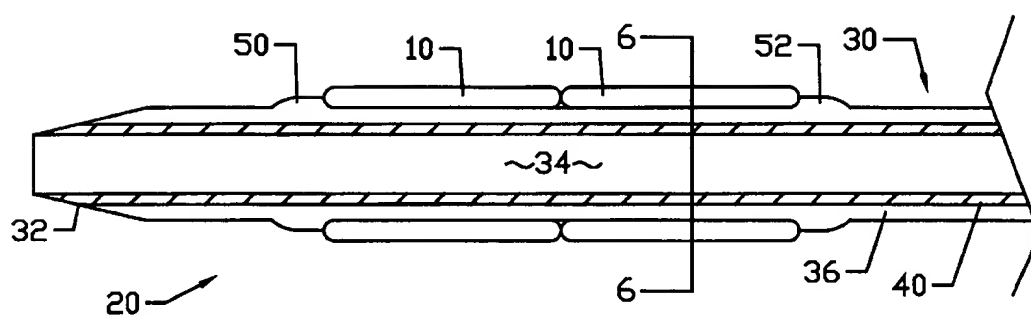
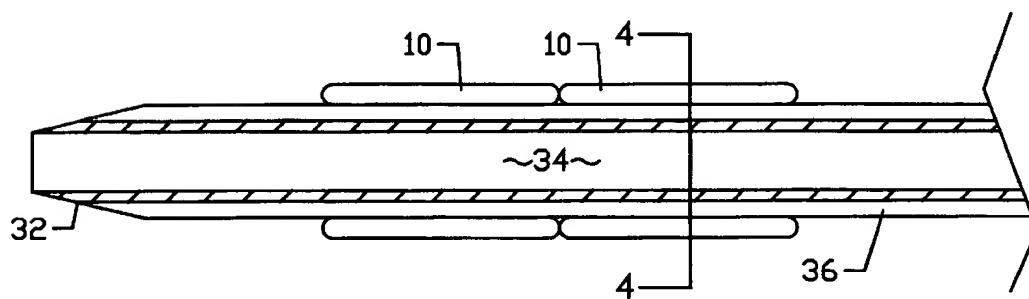


FIGURE 2



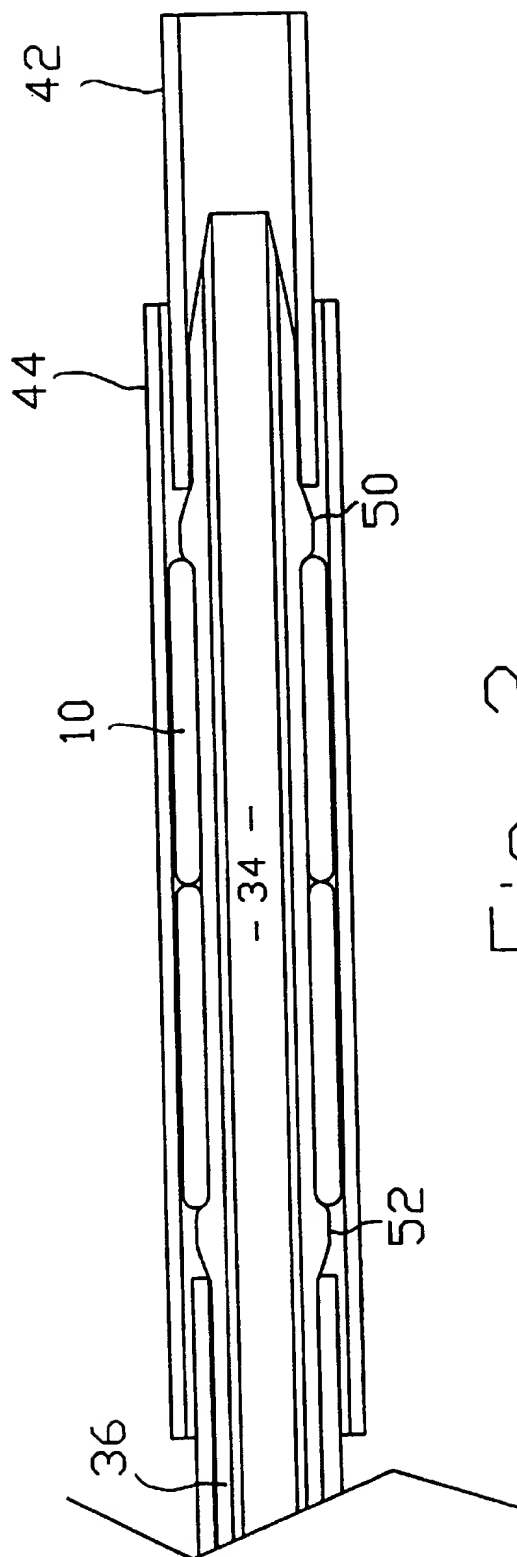


Fig. 3

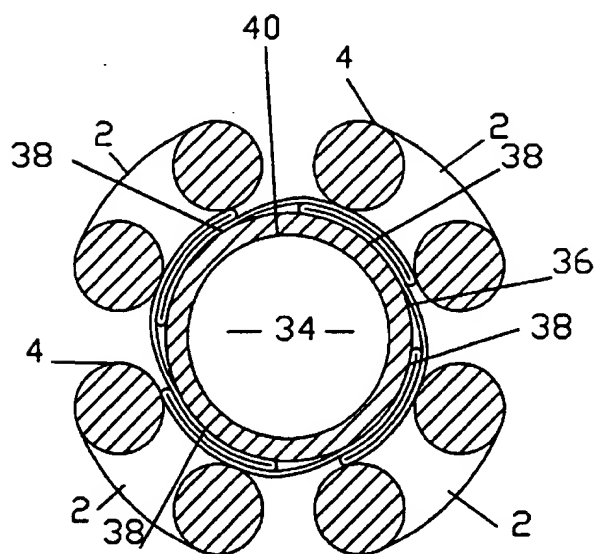


Fig. 4

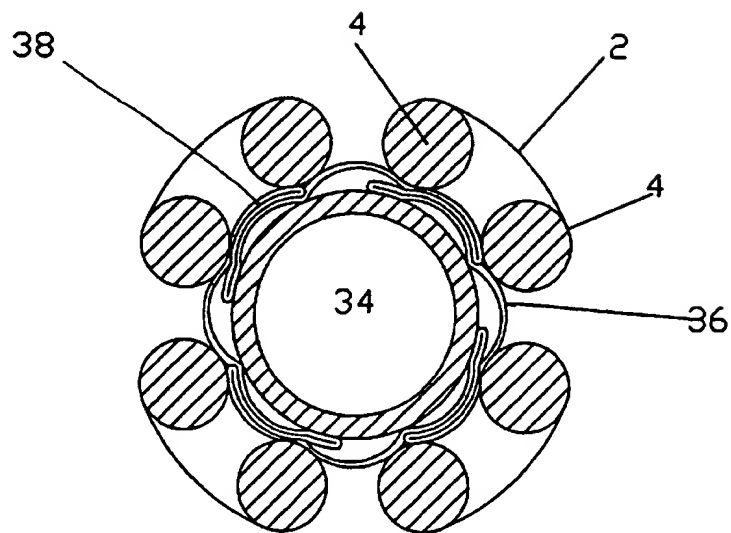


Fig 5

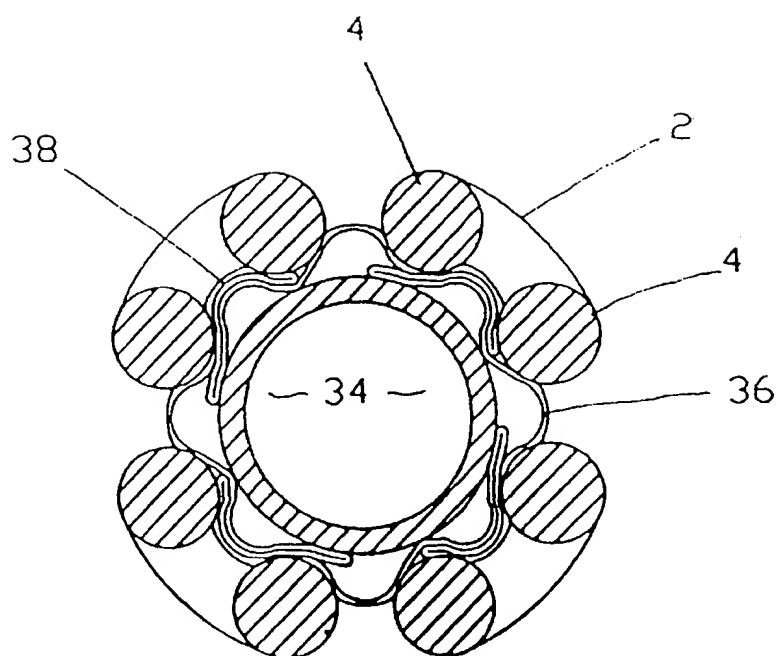


Fig 6

FIGURE 7

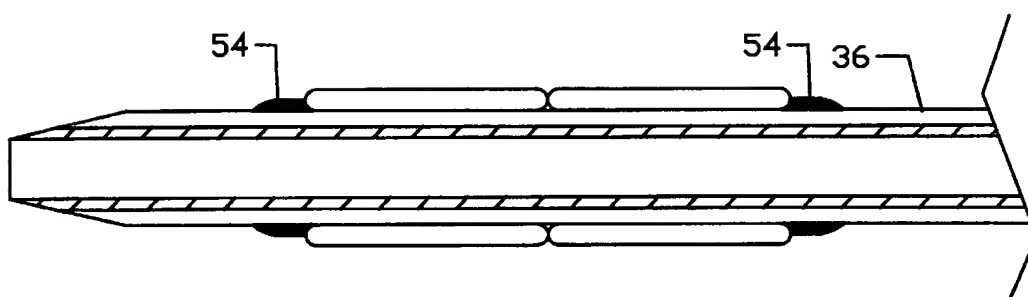
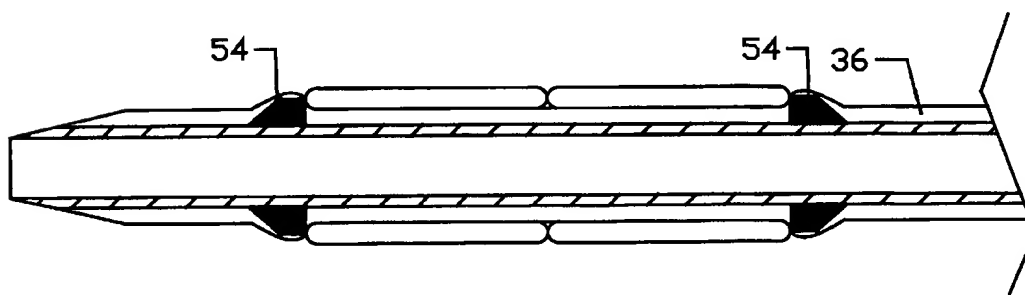


FIGURE 8



STENT DELIVERY AND DEPLOYMENT METHOD

This application is a continuation-in-part of U.S. patent application Ser. No. 08/326,023, filed on Oct. 19, 1994 abandoned.

FIELD OF THE INVENTION

This invention relates to medical implant devices. More specifically, the invention relates to a stent encapsulated by an expandable balloon for delivery and deployment in narrowing coronary or peripheral vessels in humans.

DESCRIPTION OF THE PRIOR ART

Cardiovascular disease, including atherosclerosis, is the leading cause of death in the U.S. The medical community has developed a number of methods and devices for treating coronary heart disease, some of which are specifically designed to treat the complications resulting from atherosclerosis and other forms of coronary arterial narrowing.

An important development for treating atherosclerosis and other forms of coronary narrowing is percutaneous transluminal coronary angioplasty, hereinafter referred to as "angioplasty" or "PTCA". The objective in angioplasty is to enlarge the lumen of the affected coronary artery by radial hydraulic expansion. The procedure is accomplished by inflating a balloon within the narrowed lumen of the coronary artery. Radial expansion of the coronary artery occurs in several different dimensions, and is related to the nature of the plaque. Soft, fatty plaque deposits are flattened by the balloon, while hardened deposits are cracked and split to enlarge the lumen. The wall of the artery itself is also stretched when the balloon is inflated.

Angioplasty is typically performed as follows: A thin walled hollow guiding catheter is introduced into the body via a relatively large vessel, such as the femoral artery in the groin area or the brachial artery in the arm. Once access to the femoral artery is achieved, a short hollow sheath, or guiding catheter, is inserted to maintain a passageway during the procedure. The flexible guiding catheter must negotiate an approximately 180 degree turn through the aortic arch to descend into the aortic cusp where entry may be gained to either the left or the right coronary artery, as desired.

After the guiding catheter is advanced to the area to be treated by angioplasty, a flexible guidewire is inserted into the guiding catheter through an expandable balloon (described infra) and advanced to the area to be treated. The guidewire is advanced across the lesion, or "wires" the lesion, in preparation for the advancement of a balloon catheter having an expandable balloon portion composed of polyethylene, polyvinyl chloride, polyolefin, or other suitable substance, across the guide wire. Currently, most balloons utilize two folded wings wrapped around the hollow catheter tube. The balloon catheter is placed into position by sliding it along the guide wire. The use of the relatively rigid guide wire is necessary for steerability to advance the catheter through the narrowed lumen of the artery and to direct the balloon, which is typically quite flexible, across the lesion. Radiopaque markers in the balloon segment of the catheter facilitate positioning across the lesion. The balloon catheter is then inflated with contrast material to permit fluoroscopic viewing during treatment. The balloon is alternately inflated and deflated until the lumen of the artery is satisfactorily enlarged.

Unfortunately, while the affected artery generally can be enlarged, in some instances the vessel restenoses

chronically, or closes down acutely, negating the positive effect of the angioplasty procedure. In the past, such restenosis has frequently necessitated repeat PTCA or open heart surgery. While such restenosis does not occur in the majority of cases, it occurs frequently enough that such complications comprise a significant percentage of the overall failures of the PTCA procedure, for example, twenty-five to thirty-five percent of such failures.

To lessen the risk of restenosis, various devices have been proposed for mechanically keeping the affected vessel open after completion of the angioplasty procedure. Such mechanical endoprosthetic devices, which are generally referred to as stents, are typically inserted into the vessel, positioned across the lesion, and then expanded to keep the passageway clear. Effectively, the stent overcomes the natural tendency of the vessel walls of some patients to close back down, thereby maintaining a more normal flow of blood through that vessel than would be possible if the stent were not in place.

Various types of stents have been proposed, including self-expandable and expandable stents, although to date none has proven completely satisfactory. Expandable stents generally are conveyed to the area to be treated on balloon catheters or other expandable devices. For insertion, the stent is positioned in a compressed configuration along the delivery device, such as a balloon catheter defining a balloon with two folded and wrapped wings, to make the stent diameter as small as possible. After the stent is positioned across the lesion, it is expanded by the delivery device, causing the length of the stent to contract and the diameter to expand. Depending on the materials used in construction of the stent, the stent maintains the new shape either through mechanical force or otherwise.

One such expandable stent for delivery on a balloon catheter is the Palmaz stent (U.S. Pat. No. 4,733,665) which may be thought of as a stainless steel cylinder having a number of slits in its circumference, resulting in a mesh when expanded. The stainless steel cylinder is compressed onto the outside of a non-expanded balloon catheter which includes stent retainer rings at each end of the stent to help to maintain the stent on the balloon. Also, it is advisable to place a sheath over the compressed stent and balloon assembly to retain the stent on the balloon and to create an even outer surface on the assembly for negotiation through the narrowed vessels. Boneau U.S. Pat. No. 5,292,331 provides a unitary wire-like stent structure configured to form a plurality of upper and lower axial peaks, and is delivered and expanded in a similar manner.

Significant difficulties have been encountered with deployment of known prior art stents, including difficulty in maintaining the stent on the balloon and in achieving symmetrical expansion of the stent when deployed. Currently, some stent delivery systems retain the stent on the delivery catheter by means of either (a) plastically deforming the stent so that it is crimped onto the balloon, or (b) having the stent exhibit a small enough internal diameter to act as an interference fit with the outside diameter of the balloon catheter. The disadvantage with these methods is that the limited amount of securement between the stent and the balloon is not always adequate to insure that the stent will properly stay in place while advancing the stent to and through the target lesion. Additionally, the outer surface of the delivery device is uneven because the stent generally extends outwardly beyond the balloon and may contact a narrowed vessel wall and be displaced while the catheter negotiates a narrowed vessel. Most known expandable stent delivery systems utilize a removable sheath system on the

outside of the stent, with or without retainer rings, that is removed once the stent is at the delivery site. This method protects the stent and provides a smooth surface for easier passage through vessels, but the method increases the crossing profile of the delivery device thereby decreasing the device's ability to track through narrowed and tortuous vasculature. This and other complications have resulted in a low level of acceptance for such stents within the medical community, and to date stents have not been accepted as a practical method for treating chronic restenosis.

A long felt need exists for a delivery and deployment method for stents which ensures positional stability of the stent during delivery without the need for an external sheath, thereby substantially decreasing the cross sectional profile of the balloon delivery device, and ensures symmetrical expansion of the stent at deployment.

SUMMARY OF THE INVENTION WITH OBJECTS

The stent delivery and deployment method of this invention provides a frozen-in balloon in intimate contact with, and/or surrounding, a stent to assure stent attachment to the balloon, i.e. encapsulation. This method is especially valuable at the proximal and distal ends of the stent for delivery purposes because a smoother transition occurs between the distal and proximal surfaces of the balloon catheter and the distal and proximal ends of the stent, and it also is effective along substantially the entire length of the stent. The frozen-in balloon form is achieved by encapsulating the stent so that the balloon may expand part way around the stent and adhere thereto. The preferred method of encapsulating the stent and balloon includes the steps of compressing the stent on the outside of the balloon, placing a sheath over the compressed stent to prevent expansion, and exposing the sheathed stent and balloon to an elevated temperature while pressurizing the balloon. The elevated temperature and pressurization causes the balloon to expand from below the stent to fill at least some of the spaces between the stent and the sheath. Following expansion and exposure to an elevated temperature, the balloon and stent are cooled while maintaining pressure in the balloon, so that the balloon profile will be "frozen around" (formed and somewhat adhered to) the stent. Alternatively, heat without pressurization of the balloon may be sufficient for encapsulation when the compressive forces of the sheath against the stent, which is pressed against the heated balloon, enables encapsulation of the stent.

If desired, the encapsulated stent may include conventional retainers at the proximal and/or distal end of the balloon. Such retainers may be located on top of the balloon or within the balloon. Additionally, the balloon itself may be used to form one or more stent retainers during encapsulation. In this aspect of the invention, a space is defined between the balloon and the sheath, proximal and/or distal to the stent, so that the balloon expands to occupy the space and form one or more retainers during the encapsulation process. Retainers assist in delivery by providing a smooth transition between the encapsulated stent and the catheter surface.

The preferred balloon for the method described above defines multiple (three or more) folded and wrapped "wings" or radial extensions on a balloon delivery device to assure radially symmetrical stent expansion during deployment. The preferred balloon utilizes four wings for a Boneau stent having four axial turns at each end, and the balloon length and number of wings may be tailored to the particular

stent or stents to be deployed. By utilizing more than two wings, more symmetrical stent deployment and vessel coverage can be achieved. Symmetrical stent deployment results in symmetrical expansion and support of the target lesion thereby suggesting use of multiple folds for standard PTCA balloon catheters with or without stents.

The method of this invention may be used with most self-expanding and expandable prior art stents, such as tubular slotted stents, and including connected stents, articulated stents, and multiple connected or non-connected stents. It is preferred to use a stent apparatus such as the Boneau stent which is formed preferably from a single piece of wire defining axial bends or turns between straight segments. The stent apparatus can then be encapsulated on a balloon catheter using the inventive method, delivered to the affected vessel and expanded in place, all as described herein. Some of the intended uses include PTCA type stenting, PTA type stenting, graft support, graft delivery, INR use, GI tract use, drug delivery, and biliary stenting.

A general object of the present invention is to provide a stent delivery and deployment method that overcomes the drawbacks and limitations of the prior art.

A specific object of the present invention is to provide a stent delivery and deployment method that eliminates the need for a deployment sheath and results in a low profile device with a more regular outer surface that may be delivered through tortuous, narrowed vessel.

Another specific object of the present invention is to provide a stent delivery and deployment method which encapsulates the balloon and stent thereby securing the stent to the balloon and decreasing the profile of the stent and balloon.

Yet another specific object of the present invention is to provide a stent delivery and deployment method which includes a balloon with three or more wrapped and folded wings to ensure symmetrical deployment of the stent and expansion of the lesion to be treated.

One more specific object of the present invention is to provide an encapsulated stent and balloon have a retainer at the distal and/or proximal ends of the stent for maintaining the stent on the balloon and for forming a smooth outer surface on the encapsulated stent device.

Still another specific object of the invention is to provide a method for encapsulating the majority of expandable and self-expanding stents for treating vessels in humans.

These and other objects, advantages and features of the present invention will become more apparent upon considering the following detailed description of preferred embodiments, presented in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a longitudinal cross sectional view of two encapsulated stents and a balloon embodying the principles of the present invention and shown on a balloon catheter device.

FIG. 2 is a longitudinal cross sectional view of the stents of FIG. 1 compressed upon a balloon of a balloon catheter and shown prior to the encapsulation process.

FIG. 3 is a longitudinal cross sectional view of the stents and balloon during the encapsulation process and shown positioned within interior and exterior sheaths.

FIG. 4 is a cross sectional view taken along lines 4—4 of FIG. 2 and showing four folded and wrapped wings of the balloon beneath one of the stents.

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FIG. 5 is a cross sectional view showing the partially inflated form of the balloon around the stent.

FIG. 6 is a cross sectional view taken along lines 6—6 of FIG. 1 and showing the frozen-in form of the balloon around the stent.

FIG. 7 is a longitudinal cross sectional view of two encapsulated stents and a balloon showing retainers on the outside of the balloon.

FIG. 8 is a longitudinal cross sectional view of encapsulated stents and a balloon showing retainers on the inside of the balloon and attached to the balloon catheter.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

FIG. 1 shows an encapsulated stent assembly 20 embodying the principles of the present invention. Two stent segments 10 are shown, and it will be recognized by those skilled in the art that one or more stent segments 10 may be used depending upon the size and configuration of the narrowed vessel to be treated. Additionally, when more than one stent segment 10 is used, the segments may be connected together by articulated or rigid joints, or multiple single stent segments may be deployed on the balloon catheter 30.

The balloon catheter 30 preferably is of a low profile design defining a tapered distal tip 32, and an inner lumen 34 for insertion of a conventional guide wire (not shown). Any conventional or modified balloon catheter device may be used, such as a PTCA balloon catheter, and it is preferred that the expandable balloon portion 36 be configured on the catheter 30 so that the collapsed balloon defines three or more folded wings 38 which are wrapped around the outside of the catheter tube 40 as best shown in FIG. 4. In the embodiment in FIG. 4, the balloon 36 defines four folds 38 wrapped around the catheter tube 40 in a clockwise direction.

The preferred balloon 36 is formed from a material such as polyethylene, polyethylene terephthalate (PET), or from nylon or the like. The length and diameter of the balloon may be selected to accommodate the particular configuration of the stent to be encapsulated. The balloon may be carried on any catheter, although PTCA low profile catheters and over the wire catheters are preferred. The wings of the balloon are formed by pulling the balloon catheter through a forming tool having a generally cylindrical cross section and defining a terminal opening configured to produce the desired number of wings in the balloon. For instance, configuration of the terminal opening may include three or four slits radiating outwardly from the end of the forming tool, depending upon the number of folds to be produced. As the balloon catheter is pulled through the forming tool, the balloon is pushed through the configured terminal opening and exits having, for instance, three separate flutes. The balloon catheter bearing the fluted balloon portion then is pulled into a sheath, preferably a two part sheath made of Teflon or other suitable materials, so that the flutes fold and wrap around the catheter in a clockwise direction to form a generally spiral configuration around the catheter. The sheath-balloon catheter assembly is subjected to heat, preferably by placing the assembly in a heat set oven, to form a crease in substantially the length of each of the folded flutes. The sheath also may be of unitary construction. Following heat setting, the balloon 36 retains the creases formed in the wings and defines a generally symmetrical, cylindrical cross section, as best seen in FIG. 4.

Referring now to FIGS. 1-5, the Boneau stent is shown for illustration purposes only, and Boneau U.S. Pat. No.

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5,292,331 is hereby incorporated by reference. Each of the stent segments 10 is preferably a short, single wire stent 10 having an expandable, generally cylindrical body portion defining an inside surface and an outside surface. In the stent segments 10 shown, the single piece of wire is bent to form a plurality of upper and lower axial turns 2. The plurality of upper turns 2 are connected to the plurality of lower turns 2 by substantially straight sections 4. The axial turns 2 can be seen to permit the stent segment 10 to be compressed or expanded over a wide range while still maintaining a significant mechanical force, such as required to prevent a vessel from restenosis or recoiling.

The stent segments 10 are preferably constructed of implantable materials having good mechanical strength, such as implantable quality stainless steel wire. The outside of the stent segments may be selectively plated with platinum, or other implantable radiopaque substances, to provide improved visibility during fluoroscopy. The cross-sectional shape of the finished stent segment 10 may be circular, ellipsoidal, rectangular, hexagonal, square, or other polygon, although at present it is believed that circular or ellipsoidal may be preferable.

The minimum length of each stent segment 10, or the distance between the upper turns and lower turns 2, is determined in large measure by the size of the vessel into which the stent 20 will be implanted. Additionally, each stent segment 10 may define N number of turns, N being preferable between 2 and 10. In the stent segments 10 shown in the drawings, the segments define four upper and four lower axial turns 2. The stent segments 10 may be connected together by articulated or rigid joints, or they may be deployed in a multiple spaced apart, non-connected configuration. The implanted encapsulated stent assembly 20 will preferably be of sufficient length as to maintain its axial orientation with the vessel without shifting under the hydraulics of blood flow (or other fluid flow in different types of vessels), while also being long enough to extend across at least a significant portion of the affected area. At the same time, the encapsulated stent 20 should be short enough as to not introduce unnecessarily large amounts of material as might cause undue thrombosis.

Following selection of the configuration and size of a stent segment 10, or multiple connected or non-connected stent segments, the segment or segments 10 are compressed upon the outside of the balloon 36 of the balloon catheter 30 as best shown in FIGS. 2 and 4. An interior sheath 42 is placed over each end of the balloon catheter 30, and an exterior sheath 44 is placed over the interior sheath 42 to cover the stent segments 10 and overlap with the interior sheath 42. The sheaths 42, 44 are preferably non-expandable, and of a size to accept insertion of the stent segments 10 mounted on the balloon. Sheaths 42, 44 are shown for example only, and it will be recognized by those skilled in the art that the balloon catheter and stents compressed thereon also may be placed within a mold to prevent expansion of the stent and configured to allow expansion of the balloon as desired.

Next, the balloon catheter 30 preferably is pressurized by introducing air, or an inert gas such as nitrogen, through the lumen 34 into the interior of the balloon to partially expand the balloon 36 within the sheaths 42, 44. The assembly then is exposed to an elevated temperature while maintaining pressurization of the balloon. The pressure may be, for example, approximately 70 psi, and the elevated temperature may be achieved by placing the sheathed assembly into an oven at approximately 150 degrees Fahrenheit to accomplish the heating step.

FIGS. 4-6 demonstrate, respectively, the configuration of the balloon 36 prior to pressurization, the configuration during inflation, and the frozen-in form configuration around and adhering to a stent segment 10. The balloon 36, and the wings 38, expand partially outwardly to occupy spaces around the axial turns 2 and between the straight sections 4 so that the balloon 36 and the stent segments 10 are in intimate contact. Those skilled in the art will recognize that expansion of the balloon also depends upon the form of the particular stent selected for encapsulation. Pressure between the stent and the balloon during heating and balloon pressurization causes an adherence upon cooling. Adherence is required for encapsulation which includes both intimate contact between the stent and the balloon as well as contact where the balloon surrounds at least a portion of the stent.

Alternatively, pressurization of the balloon during the heating step is not required where the sheaths 42, 44 fit tightly around the stent-balloon assembly. Pressure radiating inwardly from the sheaths 42, 44 to press against the stents 10 causes the stents 10 to press against the heated balloon to achieve encapsulation.

Following heating, the balloon-stent assembly is removed from the heat and allowed to cool within the sheath. In those cases where the balloon has been pressurized during heating, the internal pressure is maintained. Cooling sets the shape of the balloon 36 which adheres to the stent 10 following cooling, thereby allowing removal of the sheaths 42, 44 for delivery of the assembly 20 within a vessel. Because of the adherence between the stent segment 10 and the balloon 36 of the encapsulated stent assembly 20 and the more regular surface area created by encapsulating stent assembly segments, the encapsulated stent assembly 20 may be delivered without an external sheath.

As best shown in FIG. 3, and in FIG. 1, the encapsulated stent assembly 20 may include a distal retainer 50 and/or a proximal retainer 52. The retainers 50, 52 further secure the stent segment 10 to the balloon 36 and create a smooth transition between the balloon/stent area of the delivery device and the distal and proximal surfaces of the delivery device of the encapsulated stent assembly 20. The retainers 50, 52 may be formed by the balloon itself during the encapsulation process, with the configuration of the formed retainers 50, 52 determined by the dimensions of the spaces between the inner sheath 42 and the stent segments 10. Formed retainers 50, 52 may be tapered or non-tapered. Alternatively, conventional retainers 54 may be attached over the balloon 36 prior to encapsulation, as shown in FIG. 7, or the retainers 54 may be placed within the balloon 36, as shown in FIG. 8. One or two retainers 54 may be used, and conventional retainers may be made from any implantable material, such as implantable stainless steel or polymers. Depending upon the configuration of the encapsulated stent assembly 20, retainers generally range in length from 0-20 mm.

The encapsulated stent assembly 20 is delivered to the desired site with or without a guiding catheter and using a conventional guidewire for steerability to negotiate the area to be treated. Conventional radiopaque markers and fluoroscopy may be used with the device for positioning the encapsulated stent assembly and for viewing the expansion procedure. Once the encapsulated stent assembly is in place across the lesion, the balloon may be inflated in a conventional manner. In the embodiment shown in FIGS. 4-6, the four wings 38 expand evenly to form four, symmetrical expanded flutes which symmetrically expand the inner diameter of the encapsulated stent outwardly by increasing the angle at the axial bends. During typical balloon expansion

pressures of approximately 6 atmospheres or 90 psi, occurring within the human body and at body temperature, the heat set creases dissipate. The folded and wrapped wing configuration of the balloon ensures that the balloon will provide radially uniform inflation so that the stent will expand substantially equally along each of the peaks. Uniform expansion of the lumen of the vessel occurs with uniform, symmetrical expansion of the encapsulated stent and balloon. The amount of inflation, and commensurate amount of expansion of the stent, may be varied as dictated by the lesion itself, making the stent assembly of the present invention particularly flexible in the treatment of chronic restenosis and abrupt reclosure.

Because of the inflation of the balloon and expansion of the arterial wall of the vessel, the arterial wall bulges radially. At the same time, the plaque deposited within the intima of the vessel is displaced and thinned, and the stent is embedded in the plaque or other fibrotic material adhering to the intima of the vessel.

Following inflation of the balloon and expansion of the encapsulated stent within the vessel, the balloon is deflated so that it pulls away from the stent for removal. The deflated balloon generally forms from 1½ to 2¾ wings, including a generally U-shaped deflated form, and the deflated wings do not retain the creases created by the heat setting balloon formation process discussed above. The deflated balloon easily folds around the balloon catheter for removal.

The exterior wall of the vessel attempts to return to its original shape through elastic recoil. The stent, however, remains in its expanded form within the vessel, and prevents further recoil and restenosis of the vessel. The stent maintains an open passageway through the vessel. Because of the low mass of the preferred support device of the present invention, thrombosis is less likely to occur. Ideally, the displacement of the plaque deposits and the implantation of the stent will result in a relatively smooth inside diameter of the vessel.

While the primary application for the stent is presently believed to be treatment of cardiovascular disease such as atherosclerosis or other forms of coronary narrowing, the stent of the present invention may also be used for treatment of vessels in the kidney, leg, carotid, or elsewhere in the body. In such other vessels, the size of the stent may need to be adjusted to compensate for the differing sizes of the vessel to be treated.

While this invention has been described in connection with preferred embodiments thereof, it is obvious that modifications and changes therein may be made by those skilled in the art to which it pertains without departing from the spirit and scope of the invention. For instance, the encapsulation method and deployment is not limited to any particular expandable stent device. Accordingly, the aspects discussed herein are for illustration only and should not limit the scope of the invention herein which is defined by the claims.

What is claimed is:

1. An endovascular support device for implantation in a vessel within the human body comprising:

at least one compressible stent means mounted on a balloon of a balloon catheter; and

wherein said at least one compressible stent means is encapsulated by said balloon of said balloon catheter.

2. The endovascular support device of claim 1 wherein the balloon is adhered to the compressible stent means when encapsulated.

3. The endovascular support device of claim 1 further comprising at least one retainer means for facilitating delivery of the encapsulated stent means for implantation.

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4. The endovascular support device of claim 3 wherein the balloon forms the at least one retainer means.

5. The endovascular support device of claim 1 wherein the stent means comprises at least one expandable member bent to form a plurality of substantially straight, non-overlapping sections connected by axial bends.

6. A method for treating narrowing of vessels within humans comprising the steps of:

providing at least one endovascular support device;

mounting the at least one endovascular support device on a balloon of a balloon catheter;

anchoring the at least one endovascular support device to the balloon by encapsulation of the at least one endovascular support device by the balloon;

advancing the balloon catheter and the at least one encapsulated endovascular support device to an area to be treated within the vessels;

inflating the balloon of the balloon catheter to expand the at least one encapsulated endovascular support device within the area to be treated; and

deflating the balloon of the balloon catheter so that the balloon pulls away from the at least one endovascular support device.

7. A delivery system for an endovascular support device comprising:

a balloon catheter having a catheter body and a balloon; means for selectively inflating and deflating said balloon;

at least one endovascular support device mounted on said balloon, said at least one endovascular support device having a first diameter for intraluminal delivery and a second expanded diameter for deployment in a vessel; wherein said balloon at least partially surrounds at least a portion of said at least one endovascular support device thereby securing said at least one endovascular support device to said balloon for intraluminal delivery.

8. The delivery system according to claim 7 wherein the at least one endovascular support device is retained in indentations formed in said balloon.

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9. The delivery system according to claim 7 wherein the balloon adheres to the at least one endovascular support device.

10. The delivery system according to claim 7 further comprising at least one retainer means for facilitating delivery of said at least one endovascular support device to a predetermined location within a vessel.

11. The delivery system according to claim 10 wherein the balloon forms the at least one retainer means.

12. The delivery system according to claim 7 wherein the at least one endovascular support means comprises at least one expandable member in the form of a plurality of substantially straight segments connected by axial bends.

13. The delivery system according to claim 12 wherein said at least one expandable member is mounted onto said balloon to have an interior diameter D_i and wherein portions of said balloon protrude through said substantially straight segments to have a diameter greater than D_i .

14. A method for treating narrowing of vessels within humans comprising the steps of:

introducing a stent delivery system into a vessel, the stent delivery system comprising at least one endovascular support device mounted on a balloon of a balloon catheter, the at least one endovascular support device anchored to the balloon by encapsulation of the at least one endovascular support device by the balloon;

advancing the stent delivery system to an area to be treated within the vessels;

inflating the balloon of the balloon catheter to expand the at least one encapsulated endovascular support device within the area to be treated; and

deflating the balloon of the balloon catheter so that the balloon pulls away from the at least one endovascular support device.

* * * * *



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Maintenance Fee Statement

5836965

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1 124	5,836,965	1551	880	0	08/478,192	11/17/98	06/07/95	04	NO	PAID

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